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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,668	10/02/2003	Gary Jay Morris	73/.64	1054

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EXAMINER	
GISHNOCK, NIKOLAI A	
ART UNIT	PAPER NUMBER
3714	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/677,668	Applicant(s) MORRIS, GARY JAY	
	Examiner Nikolai A. Gishnock	Art Unit 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11,13-16,19-23,25-47 and 50-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11,13-16,19-23,25-47 and 50-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In response to the Applicant's remarks, filed 3/5/2007, claims 5, 12, 17, 18, 24, 48, & 49 are cancelled. Claims 1-4, 6-11, 13-16, 19-23, 25-47, & 50-57 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 6, 9, 14-16, 19, 26, 28, 29, 32, 35, 36, 39, 44-47, 50-54, & 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Roucka (US 2,556,043), hereinafter known as Roucka. Roucka discloses an apparatus for simulating human blood pressure cycles [Claims 1, 29, & 39], and simulating normal and abnormal human blood pressure (simulated pathological factors, 1:18-31) [Claim 19] and providing a tactile interface [Claims 1 & 19] comprising: an element or chamber to generate pressurized fluid external to a pressure vessel (pulsation pumps, 1:49-52) [Claims 1, 19, 29, 36, & 39]; where the pressurized fluid is pneumatically conveyed to the inside of the pressure vessel or chamber [Claims 1, 29, 36, & 39] having at least one movable or distendable surface (flexible rubber tube, Fig. 1, Item 124) [Claims 4, 19, 29, & 39] whereby a human senses, through touch, pressure amplitudes within the pressure vessel containing the pressurized fluid (3:71-74) [Claims 1, 19, 29, 36, & 39], simulated human blood pressure levels are maintained and regulated within the pressure vessel (arteriol

pressure, 7:19-37; the pressures being simulated are inherently human blood pressures because the circulation of blood in human beings is simulated by Roucka, 1:1-5) [Claims 1, 36, & 39]; and the simulated human blood pressure levels, comprising normal and abnormal human blood pressures (fatiguing of the heart muscle can be imitated, 4:65-69) [Claim 19], cyclically oscillate between diastolic and systolic pressure levels with a frequency equivalent to a human cardiac pulse rate (6:14-20; the pressure generated during a stroke by diaphragm pump D would inherently simulate the systolic pressure, analogous to the maximum arterial pressure occurring during the pumping action of the left ventricle, see 3:19-21; the pressure generated in the interval between pumping strokes would inherently simulate the diastolic pressure, analogous to the minimum arterial pressure during which the heart chambers are filling with blood) [Claims 1, 19, 29, 36, & 39], and a visual indicator to display indicia which specify pressure amplitudes or magnitudes of the pressurized fluid within the pressure vessel or elastomeric hollow bulb [Claims 19, 42, & 56], including an analog display [Claims 28 & 35] (manometers 64 & 76, 3:35-57), wherein the apparatus is not used to measure an actual blood pressure of a human (artificial circulatory system, 1:18-31) [Claim 29], and a user-operated electronic control to set at least one of a pressure level and pulse rate to be simulated (pumps are driven by a motor, which inherently can be operated electronically, 2:22-25; the speed at which the pumps are run inherently sets the pulse rate) [Claim 39]. Roucka discloses at least one pressure sensor to determine the pressure level within the pressure vessel (manometers 64 & 76, 3:35-57) [Claim 6]. Roucka discloses where the element to generate pressurized fluid is at least one electric powered pump (pump A is driven by cam 9 which is in turn driven by an electric motor, 2:6-25) [Claims 9 & 32]. Roucka discloses where the pressure vessel is comprised of an elastic walled (rubber) closed tube where the cyclic, simulated blood pressure levels or amplitudes inside the tube are sensed by human gripping of the tube (rubber tube 124, 6:14-20) [Claims 14 & 26]. Roucka discloses at least one user operable control to select minimum and maximum limits of pressure within the pressure vessel to simulate systolic and diastolic blood pressure levels (adjusting screws 55 & 57, 3:26-34) [Claim 15]. Roucka discloses at least one user operable control to set a simulated cardiac pulse rate for the simulated human blood pressure cycles (adjustable control lever 6, for motor friction drive for pumps A-D, 2:15-25) [Claims 16 & 44-47]. Roucka discloses a user-operated control to switch at least the human systolic blood pressure level, or the pressure amplitudes, between normal and abnormal values (adjustment of lever controlling friction gear 120, controlling the number of pulses per minute, 4:40-46), and between normal and abnormal simulated blood pressure cycles (adjusting lever 6 limits the feed to the pump, imitating a weak heart muscle, 4:59-69; also 5:26-6:13) [Claims 50-54].

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 2, 3, 10, 20, 21, 23, 30, 31, 37, 38, 40, 41, & 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roucka, in view of Futcher et al. (US 5,772,413), hereinafter known as Futcher. Roucka teaches all the features as described in the rejections of claims 1, 19, 29, & 36 above. What Roucka fails to teach is where the pressurized fluid is a gas [Claims 2, 20, 30, 37, & 40] or a substantially segregated mixture of gas and liquid [Claims 3, 21, 31, 38, & 41]. However, Futcher discloses where the fluid is a gas (Column 3, Lines 56-57), and where the fluid is a substantially segregated mixture of a liquid and a gas (liquid in manometer, Figure 1, Element 2). Because the circulation simulator of Roucka works with diaphragm pumps, using a gas or a segregated mixture would be possible, because diaphragm pumps are capable of pumping air. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used gas as the pressurized fluid, along with liquid-filled manometers, as described in Futcher, in the circulatory simulator of Roucka, in order to allow excess pressure to bleed from an open system without concern over recovery of the fluid [Claims 2, 3, 20, 21, 30, 31, 37, 38, 40, & 41]. What Roucka further fails to teach is where the pressure vessel comprises an elastomeric hollow bulb that can be held in a human hand, and internal pressure amplitudes of fluid within the bulb are sensed by human touch [Claims 10, 23, & 57]. However, Futcher discloses where the pressure vessel comprises an elastomeric hollow bulb that can be held in a human hand, and internal pressure amplitudes of fluid within the bulb are sensed by human touch (patient manually squeezes the bulb to create pressure on the manometer, Column 4, Lines 1-3). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have affixed the elastomeric hollow bulb of Futcher pneumatically to the end of the rubber tube of Roucka, in order to make it easier for a human hand to grip and feel the pressure generated in the circulatory simulator of Roucka [Claims 10, 23, & 57].

6. Claims 7, 8, 13, 25, 27, & 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roucka, in view of Tumey et al. (US 5,991,654), hereinafter known as Tumey. Roucka teaches all the features as demonstrated in the rejection of claims 1 & 19 above. What Roucka fails to teach is where the pressure vessel comprises an inflatable cuff whereby the periodic pressure amplitudes inside the cuff are sensed by human touch [Claims 13 & 25]. However, Tumey teaches the use of an air cuff that is periodically or cyclically inflated and deflated to apply periodic pressure to a patient's limb (8:9-41). Because the cuff is fastened to a patient, it is inherent that the pressure amplitudes would be sensed by human touch. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have substituted the air cuff of Tumey for the flexible rubber tube in Roucka, for the purpose of allowing the pressure vessel to be fastened onto a patient's limb, so that the patient can feel the pressure amplitudes without having to grip the vessel [Claims 13 & 25]. What Roucka further fails to teach is where an electromechanically actuated pressure regulator, or an electric solenoid control valve system connected to the pressure vessel. However, Tumey teaches an electromechanically operated solenoid-controlled air vent connected to an air cuff (3:58-64). Therefore, it would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to have connected the electrically operated solenoid valve of Tumey with pressure vessel of Roucka, in order to automatically release pressure in the cuff by an electrical signal [Claims 7 & 8]. Roucka teaches a visual indicator to display indicia, which specify pressure amplitudes within the pressure vessel [Claims 19 & 42]. What Roucka fails to teach is the visual indicator comprising an electronic digital display. However, Tumey teaches a computer monitor that provides a visual aid to observe various output signals, such as cuff pressure (4:39-44). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have incorporated the electronic digital display of Tumey

with the circulatory simulation of Roucka, in order to reduce the difficulty of accurately reading a standard dial gage [Claims 27 & 34].

7. Claims 22 & 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roucka, in view of Baldwin (US 4,773,865), hereinafter known as Baldwin. Roucka teaches all the features as demonstrated in the rejection of claims 19 & 29 above. What Roucka fails to teach is where the pressurized fluid is generated by at least one manually operated pump [Claims 22 & 33]. However, Baldwin teaches a bulb syringe for pumping fluid (4:24-28). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to simulate pressure and pulse with manual pumps, as taught by Baldwin, in the circulatory simulator of Roucka, in order to inexpensively construct the simulator [Claims 22 & 33].

8. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, in view of Roucka. Baldwin teaches an apparatus for simulating human blood pressure and providing a tactile interface comprising: a first elastomeric hollow bulb (bulb syringe 62) to pressurize fluid by manual compression of the bulb; a second elastomeric hollow bulb (simulated femoral artery 52') pneumatically connected to the first bulb through a bi-directional flow connection (tubes 52, 52', 54, & 56) such that the pressure in the second bulb is controlled by the amount of manual compression of the first bulb; the second elastomeric hollow bulb providing a tactile interface to a human subject where the human subject physically senses fluid pressure magnitudes internal to the second bulb by gripping with at least one hand (4:24-28; squeezing the bulb inherently provides the fluid pressure the student uses to feel the simulated pulse). What Baldwin fails to teach is a visual indicator to display indicia, which specifies pressure magnitudes within the second elastomeric hollow bulb [Claim 42]. However, Roucka teaches a visual indicator to

display indicia, which specify pressure amplitudes or magnitudes within the pressure vessel or elastomeric hollow bulb (manometers 64 & 76, 3:35-57). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have connected a visual pressure indicator, as in Roucka, to the simulated femoral artery of Baldwin, in order to facilitate locating the simulated artery by pressure or pulse [Claim 42].

9. Claims 11, 43, & 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roucka and Baldwin, in view of claims 1, 19, & 42 above, and further in view of Frazier (US 6,669,624), hereinafter known as Frazier. Roucka teaches all the features as demonstrated in the rejections of claims 1 & 19 above. Baldwin and Roucka teach all the features as shown in the rejection of claim 42, also above. What Roucka and Baldwin fail to explicitly teach is an incompressible, non-liquid member positioned within the second elastomeric hollow bulb such that substantial portions of the internal surfaces of the bulb are held in contact with the incompressible member by manually squeezing the bulb [Claims 10, 43, & 55]. However, Frazier teaches a heart-assist pump comprising a flexible balloon catheter, inflated and deflated by gas pressure, with an incompressible lumens within the balloon for conveying gas to and from the balloon (Column 6, Lines 7-28 and Figure 2, Elements 8 and 14). The incompressible member taught by Frazier would be incorporated inside the pressure vessels of either Roucka or Baldwin, and aid in the uniform inflation and deflation of the pressure vessel. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have fabricated the pressure vessels as taught by Roucka and Baldwin with the incompressible member of Frazier, in order to allow the bulb to withstand rapid cyclic inflation and deflation [Claims 11, 43, & 55].

Response to Arguments

10. Applicant's arguments, see pages 14-15, filed 3/5/2007, with respect to claims 1-4, 6-11, 13-18, 39-41, 48-50, & 53 have been fully considered. Due to the amendments to the claims removing the electronic control unit, the 35 USC §112 ¶1 rejection of the office actions of 4/4/2006 and 2/2/2007 has been withdrawn.

11. Applicant's arguments, see page 16, line 1 through page 18, line 11, filed 3/5/2007, with respect to the rejection(s) of claim(s) 1 and 13 under 35 USC §102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, and necessitated by Applicant's amendments, a new ground(s) of rejection is made in view of Roucka and Tumey.

12. Applicant's arguments, see page 18, line 12 through page 19, line 6, filed 3/5/2007 have been fully considered but they are not persuasive. The pressure in the vessel of Futcher depends on the restrictor valves 15 and 114 (4:8-19 and 8-13) as much as the frequency of squeezing. The accuracy of pulse rate and blood pressure is as measured, not as generated. Futcher does not teach away from the invention because the frequency and force used to squeeze the bulb, as well as the diameter and configuration of the restrictor, would feel accurate to a human's sense of touch, as claimed, because human senses are not nearly as accurate as a measurement device, such as a manometer.

13. Applicant's arguments with respect to claims 7-9, 17, 22, 25, 27, 32-34, & 42 have been considered but are moot in view of the new ground(s) of rejection, necessitated by Applicant's amendment.

14. Applicant's arguments, see page 20, line 20 through page 21, line 17, filed 3/5/2007 have been fully considered but they are not persuasive. Baldwin teaches feeling a pulse rate in

a simulated artery, where the simulated pulse rate is conveyed as cyclic pressures generated via a squeeze bulb (4:24-28).

15. Applicant's arguments, see pages 21, line 18 through page 22, line20, filed 3/5/2007, have been fully considered but they are not persuasive. Frazier recites an incompressible member inside an elastomeric bulb as shown by Figure 2, Item 14. Futcher teaches an elastomeric bulb in Figure 1, Item 3. The examiner has relied on the teachings of Futcher and Frazier to show how an incompressible member as in Frazier, used inside an elastomeric bulb such as in Futcher, would be positioned such that substantial portions of the internal surfaces of the bulb are in contact with the member, an would indeed be functional for that purpose. The structural components as claimed could achieve this purpose, and so the references are not relied upon to teach inflation of a catheter balloon. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to have an incompressible member to inflate or deflate an elastomeric bulb rapidly and efficiently is taught in Frazier (6:15-19). This teaching applied to the blood pressure simulator of Futcher or Roucka would not render them non-functional, because an incompressible member of sufficient strength and thickness, as disclosed by Frazier, exists that could be properly inflated and deflated while gripped by a human hand. In response to applicant's argument that Frazier is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was

concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Frazier is both in the field of Applicant's endeavor, as it related to medical apparatus used to apply pressure comparable to human blood pressure, and also solves the same problem as Applicant's, providing consistent feel (that is, incompressible feel) for the subject during the simulation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai A. Gishnock whose telephone number is 571-272-1420. The examiner can normally be reached on M-F 8:30a-5p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3/31/2007

KATHLEEN MOSSER
PRIMARY EXAMINER